REMARKS

Pending claims 1-4 and 7 have been cancelled. Although applicant does not acquiesce in the Examiner's rejection of these claims, the claims have been cancelled in the interest of expediting prosecution. Applicant reserves the right to pursue the cancelled subject matter in continuing applications. Some of this subject matter is currently being prosecuted in commonly owned co-pending U.S. application ser. no. 10/152,147.

The Rejection under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 1-4, 7 and 11 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art the inventors, at the time the application was filed, had possession of the claimed invention. Claims 1-4, and 7 have been cancelled.

The Examiner asserts that the specification does not support the negative proviso added to the claims "a patient having a diet wherein carbohydrate intake is not restricted" and that, to the contrary, pages 8-10 of the specification refer to low carbohydrate intake and its physiological effects, such as ketone body production.

It is true that the specification at page 8 describes that normally the body produces small amounts of ketone bodies, and that a low carbohydrate diet and fasting result in increased blood ketone levels. In addition, the specification at page 9-10 explains the differences between medium chain triglycerides (MCTs) and long chain triglycerides (LCT) and their metabolic fate. The specification explains that MCTs are quickly converted to medium chain fatty acids, whose major metabolic fate is oxidation to large amounts of ketone bodies "*regardless of the metabolic state of the organism.*" (page 10, lines 7-8, emphasis added). That is, regardless of the amount of carbohydrate intake, or regardless of fasting.

Nowhere in the instant specification is it taught or suggested that carbohydrate levels be constrained in order to practice the claimed invention. In fact, the specification in the EXAMPLES section provides exemplary formulations which include carbohydrates. Example 2B, for instance, provides a formulation for a powdered beverage utilizing maltodextrin and sucrose. Example 2C teaches a food bar with a high content of corn syrup solids. These Examples make it implicitly clear that a patient's carbohydrate intake not be restricted.

Applicant submits that the explanation on page 9, line 13 to page 10, line 9, coupled with the teaching of formulations which include carbohydrates clearly supports the limitation "a patient having a diet wherein carbohydrate intake is not restricted." "The invention claimed does not have to be described in *ipsis verbis* in order to satisfy the description requirement of § 112." *In re Lukach,* 169 USPQ 795 (CCPA 1971).

The Examiner has rejected Claims 1-4, 7, and 11 under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not reasonably provide enablement for prevention of Alzheimer's. Claims 1-4, and 7 have been cancelled. Claim 11 has been amended to delete the reference to "preventing" in the interest of expediting prosecution. Applicant reserves the right to pursue claims directed to the prevention dementia of Alzheimer's type, or other loss of cognitive function caused by reduced neuronal metabolism in a continuing application.

The Rejection under 35 U.S.C. § 102(b)

The Examiner has rejected Claims 1, 7, and 11 under 35 U.S.C. § 102(b) as being anticipated by Blackburn, U.S. Pat. No. 4,528,197. The Court of Appeals for the Federal Circuit has stated that anticipation requires the presence in a single prior art reference of each and every element of the claimed invention. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed. Cir. 1984); *Alco Standard Corp. v. Tennessee Valley Auth.*, 1 U.S.P.Q.2d 1337, 1341 (Fed. Cir. 1986). "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic v. Genentech Inc.*, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991) (citations omitted).

Specifically, the Examiner asserts that Blackburn teaches a method comprising administering an emulsion of MCT to a patient, and the dementia-preventing qualities of the composition are inherent in the method of Blackburn, given that a compound and its properties are inseparable.

Applicant respectfully traverses this rejection. A prior art reference must contain each and every limitation of the claimed subject matter, either expressly or inherently, to anticipate. *EMI Group N. Am., Inc., v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350 (Fed. Cir. 2001). The present invention is directed to a method of treating dementia of Alzheimer's type, or other loss of cognitive function caused by reduced neuronal metabolism. Claims 11, as amended

require providing a patient having reduced neuronal metabolism. Blackburn teaches administration of MCTs to hypercatabolic mammals. Blackburn does not teach administration of MCT prodrugs to mammals having reduced neuronal metabolism. Because Blackburn does not teach this element of Claim 11, Blackburn can not anticipate Claim 11. Reconsideration is respectfully requested.

The Rejection under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 1-4, 7 and 11 under 35 U.S.C. § 103(a) as being unpatentable over Veech, U.S. Patent No. 6,316,038. Claims 1-4, and 7 have been cancelled. The Examiner bears the burden of establishing a *prima facie* case of obviousness (Section 103). In determining obviousness, one must focus on Applicant's invention as a whole. *Symbol Technologies Inc. v. Opticon Inc.*, 19 U.S.P.Q.2d 1241, 1246 (Fed. Cir. 1991). The primary inquiry is:

> whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have had a reasonable likelihood of success . . . . Both the suggestion and the expectation of success must be found in the prior art, not in the applicant's disclosure.

In re Dow Chemical, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). In summary, the Examiner asserts on page 5 of the office action that Veech (USPN 6,316,038) teaches a method for treating Alzheimer's disease and it's symptoms and manifestations, including dementia, employing a ketogenic (medium chain triglycerides) diet. The Examiner also asserts that Veech teaches an example of a ketogenic diet wherein at each of the three meals the patient consumes 48-50 g of fat, increase of ketone bodies is effective in the treatment of Alzheimer's disease.

In the explanation of the nonpersuasiveness of Applicant's arguments, the Examiner asserts that the portions of Veech cited by the Applicant are sections of the reference in which Veech describes the prior art and its shortcomings (e.g., col. 9). Applicant respectfully points out that it is these very portions of Veech that were used by the Examiner in making the previous rejections, and also, in making the present rejection (see page 6 of office action, paper number 16).

Applicant reiterates arguments made in previous correspondence regarding Veech. Namely, Veech provides descriptions of ketogenic diets in which fat intake is high and carbohydrates are limited. Although Veech provides that the intake of high amounts of fat,

whether long-chain or medium-chain triglycerides, can increase blood ketone levels, this result occurs only in the context of a highly-regimented diet in which carbohydrate levels are limited. Veech explicitly states at col. 9, lines 62-65, that "Either oral or parenteral administration of free fatty acids or triglycerides can increase blood ketones, *provided carbohydrate and insulin are low to prevent re-esterification in adipose tissue.*" (emphasis added).

The instant specification at page 9-10 explains the differences between medium chain triglycerides (MCTs) and long chain triglycerides (LCT) and their metabolic fate. The specification explains that MCTs are quickly converted to medium chain fatty acids, whose major metabolic fate is oxidation to large amounts of ketone bodies regardless of the metabolic state of the organism. Thus, contrary to the teachings of Veech, the instant specification teaches that administration of MCT outside the context of the ketogenic diet can raise blood ketone levels.

The present claim requires the administration of medium chain triglyceride prodrug to patients. Veech does not teach the administration of medium chain triglyceride prodrug to patients. The Examiner has not provided an explanation of why the teachings of Veech with regard to MCTs would be modified to arrive at the claimed subject matter of MCT prodrugs, or an explanation as to why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification. Applicant therefore submits that the Examiner has not made a *prima facie* case of obviousness referring to the disclosure of MCT prodrug administration.

The Examiner asserts on page 6 of the office action that the method of treating Alzheimer's disease taught by Veech does not require adherence to a ketogenic diet, and that Veech states at col. 17., lines 16-27 that "The advantage of using ketone bodies themselves are several. Firstly, provision of ketone bodies themselves do not require the limitation of carbohydrates, thus increasing the palatability of the dietary formulations."

The present claim requires the administration of medium chain triglyceride prodrug to patients. In this passage Veech teaches the administration of "ketone bodies themselves." Veech does not teach the administration of medium chain triglyceride prodrugs as presently claimed. (Veech does describe a ketogenic diet, however; see above). The Examiner has not provided an explanation of why the teachings of Veech with regard to ketone bodies would be modified to arrive at the claimed subject matter of MCT prodrugs, or an explanation as to why one of

ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification. Applicant therefore submits that the Examiner has not made a *prima facie* case of obviousness referring to the disclosure of ketone body administration.

Closing Remarks

Applicant believes that the pending claim is in condition for allowance. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

Date: January 14, 2004

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